

REMARKS

Status Summary

Claims 1, 3-6, 8, 10 and 11 are pending in the present application. Claim 10 is withdrawn as being drawn to a nonelected invention. Claims 1, 3-6, 8 and 11 presently stand rejected. New claim 12 is added by the present amendment. With this Amendment, claims 6 and 10 have been cancelled. Therefore, upon entry of this Amendment, claims 1, 3-5, 8, 11 and 12 will be pending.

Summary of Telephone Examiner Interview

Applicants acknowledge with appreciation the telephone interview granted by Examiner Michael Wilson to Applicants' representative, Marjorie C. Gurganus, on February 4, 2010. In the Telephone Examiner Interview, a proposed after final amendment was discussed.

Regarding the rejections of claims 1, 3-6, 8, and 11 under 35 U.S.C. § 112, applicants argued that the claims were enabled, definite, and supported by the examples in the specification. The Examiner indicated that most of the rejections appeared to be overcome by the proposed amendment as long as applicants could cite support for the enzymes recited in claim 1.

The Examiner further suggested that claim 1 should be further amended to recite "transfecting the cells with a vector encoding SF-1." The Examiner also indicated that a proposed amended claim 6 would not be entered by after final amendment.

The amendments proposed herein above are consistent with the discussion in the Telephone Interview. The Examiner agreed to consider the amended claim language. The Examiner is invited to call applicants' attorneys, Arles A. Taylor, Jr. or Marjorie C. Gurganus, at (919) 493-8000 to conduct a subsequent telephone interview to resolve any outstanding issues.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 1, 3-6, 8 and 11 are rejected under 35 U.S.C. §112, first paragraph, for an alleged lack of enablement. The U.S. Patent and Trademark Office (hereinafter the "Patent Office") contends that there is insufficient support for differentiating MSC into

any hormone-producing cells using the SF-1 **protein**. The Patent Office acknowledges that there is support for differentiating MSC, by transfecting the cells with a vector encoding SF-1, into cells that produce progesterone, androgen, and androstendione. See Official Action, page 2, lines 19-21, and page 4, lines 6-8.

After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

Claim 1 has been amended to recite that the MSC are stimulated by transfection with a vector encoding SF-1. Claim 1 has been further amended to clarify that the differentiated MSC produce steroid hormone-producing enzymes. A list of such enzymes is recited in the amended claim. No new matter has been added. As noted in the remarks above, the Patent Office acknowledges the enablement of the MSC stimulated by transfection. Support for the MSC producing the steroid hormone-producing enzymes p450scc, p450c17, HSD3b1, StAR, 3 β -HSD, p450 c21, p450 11b1, and HSD3b6 is also acknowledged by the Patent Office in the Official Action, page 4; lines 3-12, and 20. Additional support for this amendment can be found in the specification in Example 1, page 7, line 5 (for enzyme p450scc); Example 2, page 7, lines 13-14 (for enzymes p450scc, p450c17, and HSD3b1); Example 3, page 8, lines 14-15 (for enzymes p450scc, StAR, 3 β -HSD, p450 c21, and p450 11b1); and Example 5, page 9, lines 17-27 (for enzymes p450scc, HSD3b1, and HSD3b6).

Accordingly, it is respectfully submitted that the rejection of claims 1 and its dependent claims under 35 U.S.C. § 112, first paragraph should be withdrawn. Applicants further submit that claims 1, 3-5, 8, and 11 are now in proper condition for allowance and respectfully solicit a Notice of Allowance to that effect.

Claim 6 has also been rejected for lack of enablement. As indicated above, claim 6 has been canceled without prejudice or acquiescence to the contentions of the Patent Office. Accordingly, applicants respectfully submit that the rejection of claim 6 under 35 U.S.C. § 112, first paragraph is moot.

Claim Rejections - 35 U.S.C. § 112, second paragraph

The Patent Office has rejected claims 1-6, 8, 9 and 11 under 35 U.S.C. §112, second paragraph, upon the contention that the phrase, "transcription factor, SF-1" is

unclear. The Patent Office maintains that the phrase, "steroidogenic factor (SF-1)" is preferred and would overcome the rejection. Without acquiescing to the contentions of the Patent Office, applicants have amended claim 1 to recite the Patent Office's preferred language.

The Patent Office also rejects claim 1 upon the contention that the phrase "wherein the hormones produced ..." lacks antecedent basis. Without acquiescing to the contentions of the Patent Office, claim 1 has been amended. Applicants respectfully submit that the amendment obviates this rejection.

Accordingly, it is respectfully submitted that the rejection of claim 1 and its dependent claims under 35 U.S.C. § 112, second paragraph should be withdrawn. Applicants further submit that claims 1, 3-5, 8, and 11 are now in proper condition for allowance and respectfully solicit the same.

The Patent Office also contends that claim 6 is unclear. Claim 6 has been canceled. Accordingly, applicants respectfully submit that the rejection of claim 6 under 35 U.S.C. § 112, second paragraph is moot.

New Claim

New claim 12 has been added by this amendment as indicated above. Claim 12 is essentially previously presented claim 1 rewritten to recite that progesterone, androstendione, or androgen is the hormone produced by the differentiated MSC. No new matter has been added. The Patent Office acknowledges that a method of differentiating MSC into cells that produce these hormones is enabled. See Official Action page 4, lines 6-8. Additional support for this amendment can be found in Example 2, page 7, lines 25-28, of the specification as filed.

Therefore, applicants submit that new claim 12 is allowable over the prior art and respectfully solicit a Notice of Allowance to that effect.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

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If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

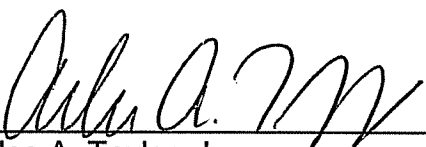
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiencies of payment, or credit any overpayment associated with the filing of this Amendment to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: 03/29/2010

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